REMARKS

Reconsideration of this application is requested. Claims 32-34 are in the case.

I. THE ANTICIPATION/OBVIOUSNESS REJECTION

Claims 32-34 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by or, in the alternative, under 35 U.S.C. §103(a) as allegedly unpatentable in view of Horrobin (US 5,198,468). The rejection is respectfully traversed.

As claimed, there is provided a method of treating a patient suffering from a neurodegenerative disorder which is memory loss. The method comprises administering to the patient a therapeutically effective amount of at least one of D-β-hydroxybutyric acid, acetoacetate, or a metabolic precursor or physiologically acceptable salt of D-β-hydroxybutyric acid or acetoacetate, thereby elevating the patient's blood levels of ketone bodies, defined as the sum total of D-β-hydroxybutyric acid and acetoacetate, to a therapeutic level effective to treat the disorder, and the patient's blood level of ketone bodies is elevated to from 0.3mM to 20mM.

The claimed method requires ketosis of 0.3 mM or more. Horrobin does not disclose (or suggest) such a level of ketosis. Withdrawal of the anticipation rejection based on Horrobin is accordingly respectfully requested.

Claim 33 has been amended to recite "...free fatty acids the metabolism of which is through β-oxidation and medium chain length triglycerides". That the free fatty acids are metabolized through β-oxidation is clear from the disclosure in paragraphs [0036] and [0037] of the present application. Medium chain length triglycerides are specified in paragraph [0044]. No new matter is entered by the amendment to claim 33.

Paragraphs [0036] and [0037] of the present application explain how free fatty acids are metabolized to provide ketosis. Free fatty acids may be provided in diet or may derive from lipolysis of triglycerides. However, some triglycerides comprise fatty acids that do not primarily proceed to metabolism by β-oxidation, as explained in paragraphs [0036] and [0037]. These in particular include the n-6 essential long chain fatty acids referred to in Horrobin (GLA, DGLA, AA, Adrenic acid and 22-5 n-6 and the n-3 essential fatty acid DHA).

The essential fatty acids are metabolized by further conversion to lengthened n-6 or n-3 fatty acids and from there to various prostaglandins, thromboxanes, leukotrienes and other physiologically active materials. Attached is a copy of a recent review of this pathway and its significance for treating various conditions (Undurti in *Lipids in Health and Disease* 2008, **7**:9).

These metabolic pathways are partly acknowledged by Horrobin (column 1):

n-6		n-3
18:2 delta-9,12(linoleic acid)		18:3 delta-9,12,15 (alpha-linolenic acid)
delta-6 desaturase	↓	
18:3 delta-6,9,12(gamma-linolenic acid)		18:4 delta-6,9,12,15
elongation	↓	
20:3 delta-8,11,14(dihomo-gamma-linolenic acid)		20:4 delta-8,11,14,17
delta-5 desaturase	↓	
20:4 delta-5,8,11,14(arachidonic acid)		20:5 delta-5,8,11,14,17
elongation	↓	
22:4 delta-7,10,13,16(adrenic acid)		22:5 delta-7,10,13,16,19
delta-4 desaturase	↓	
22:5 delta-4,7,10,13,16		22:6 delta-4,7,10,13,16,19

In contrast, the present application exemplifies free fatty acids and, in particular, medium chain triglycerides that are particularly suited to metabolism to provide ketosis. As noted earlier, the claimed invention requires production of ketosis. Horrobin does

not disclose or suggest administration of fatty acids or triglycerides to provide ketosis but, rather, to produce prostaglandins, thromboxanes and leukotrienes.

In light of the above, it is clear that Horrobin does not render obvious the use of fatty acids to provide ketosis, as that would not produce the described prostaglandins, thromboxanes and leukotrienes. One of ordinary skill would therefore not have been motivated, as of the filing date of the present application, to consult Horrobin in the context of the presently claimed invention.

Also attached is Bach *et al*: 2008 American Journal of Clinical Nutrition 26: pp950-962. Bach explains the metabolism of medium chain fatty length acids as opposed to long chain fatty length acids and why the former are more suited to provision of ketosis than the latter. It will be seen that the fatty acids of Horrobin are not only long chain (18 carbons or longer, as opposed to medium chain - i.e., C8-12), but also they contain three or more unsaturated bonds by which the distribution and ultimate metabolism are determined.

Based on the above, it is believed that withdrawal of the prior art rejection is in order. Such action is respectfully requested.

III. AMENDMENTS

Claim 2 has been amended to recite "...free fatty acids the metabolism of which is through β-oxidation and medium chain length triglycerides". Metabolism of the free fatty acids through β-oxidation is described in paragraphs [0036] and [0037] of the present application, and medium chain length triglycerides are mentioned in paragraph [0044]. No new matter is entered.

Favorable action is awaited.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____
Leonard C. Mitchard
Reg. No. 29,009

LCM:lff
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100
Attachments: Undurti in *Lipids in health and Disease*; 7:9 (2008), and Bach et al; *American Journal of Clinical Nutrition*, 26; pp. 950-962 (2008).